

**K223326 Axiom PSR System**Mar 30, 2023  
150 days to decisionK223326 · Product code: **OYK** · Orthopedic  
Source: <https://www.510kdatabase.net/k223326/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ankle Arthroplasty Implantation System (OYK)
Date received	Oct 31, 2022
Decision date	Mar 30, 2023
Days to decision	150 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Restor3d</b>
Location	Durham, NC, US
Contact	Brianna Prindle
510(k) history	11 submissions · 11 cleared · 2020-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223326/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026